Docket No. 4739

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS & INTERFERENCES

Appellants:	Eugene P. GOLDBERG, ET AL
Serial No.:	08/141,017
Filed:	October 26, 1993
For:	METHOD OF AND COMPOSITION FOR PREVENTING TISSUE DAMAGE
Art Unit:	1502
Examiner:	Edward J. Webman

REPLY BRIEF

Hon. Commissioner of Patents & Trademarks
Washington, D.C. 20231

Sir:

This Reply Brief Under 37 CFR §1.193(b) is in response to the new points of argument set forth in the Examiner's Answer mailed October 14, 1997.

In the final Office Action, the Examiner stated that the rejection of the claims was based on 35 USC §103. However, in the Answer, the Examiner's arguments appear to be directed toward showing that the reference to Balazs anticipates all of the elements of the claimed method. In other words, the 35 USC §103 based rejection is couched in 35 USC §102 type arguments and language.

It is respectfully submitted that in any rejection under 35 USC §103, novelty of the claimed invention is presumed. Thus, the initial burden is upon the Examiner to

identify the distinction(s) between the claimed invention and the disclosure(s) of the applied reference(s) and then establish a prima facie case of obviousness. See In re Carleton, 202 USPQ 165. In the present case, however, the Examiner appears to be arguing that the reference to Balazs discloses each and every element of the invention. The question then arises: Why didn't the Examiner base this ground of rejection on 35 USC §102 rather than 35 USC §103?

Appellants have in the past and will again hereinbelow establish that the method of the claimed invention is novel, i.e., that it does differ in critical respects from the methods disclosed by Balazs. However, because the Examiner has failed to shoulder his initial burden of proof, i.e., that imposed by In re Carleton, supra, appellants are at a complete loss as to (1) how to show that the Examiner has not established a prima facie case of obviousness and (2) how the evidence of record rebuts any such prima facie case of obviousness.

Before proceeding, however, appellants desire to make it clear that the Examiner's Answer has seriously compromised the issues on appeal herein since it is unclear to appellants whether the claims are rejected under 35 USC §103 or 35 USC §102. If the former, the Examiner has failed to establish a prima facie case of obviousness; indeed, the point of novelty has not been identified by the Examiner. If the

latter, the rejection has not been properly stated as being based on 35 USC §102. Of course, if the Examiner is of the opinion that the claimed invention is not novel, a new ground of rejection pursuant to 37 CFR §1.193(b) must be set forth.

The claimed method specifies "providing surfaces involved in said...surgery with a wet coating...prior to manipulation of said tissue during said surgery." The Examiner states (Answer, paragraph bridging pages 5 and 6):

> "...Applicants claim application prior to manipulation of tissue. Balazs' teaching of protection during surgical manipulation clearly indicates prior application ..." [Emphasis added.]

The sole disclosure in Balazs relied upon by the Examiner for the above argument is contained in column 15, lines 3-9[1]:

> "...HUA can be used to separate tissue surfaces. The elastoviscous quality of HUA and its biological origin provide two advantages. First, it serves as a mechanical protector of the tissue during surgical manipulation and postoperatively ..." [Emphasis added.]

All reasonable persons would agree that any surgical procedure involves a sequence of steps, namely, (1) preparation of the patient for surgery (which would include prepping

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[1] The Examiner states in the sentence bridging pages 5 and 6 of the Answer that: "applicants misquote column 15, lines 3-9, referring to 'during surgical administration' rather than the correct 'during surgical manipulation.'" It is noted, however, that in the Brief appellants were not quoting Balazs. Rather, appellants were quoting the Examiner's characterization of Balazs in the last full paragraph of page 2 of the final Office Action. The Examiner, not appellant, is guilty of misquoting Balazs.

not only the patient, but also the surgical articles and tools involved in the surgery), (2) the initiation of the surgical procedure, (3) the continuum of the surgical procedure, including its termination and (4) the post-operative procedures.

The claimed method initiates during step (1) and before step (2), i.e., before the actual surgery takes place. Appellants have found that coating all of the surfaces involved in the surgery with the specified wet coating prior to any "manipulation of the tissue during surgery" provides a totally unobvious and unexpected degree of tissue protection.

The quoted portion of Balazs unequivocally relates to events "during surgery," i.e., during step (3), after initiation of the surgical procedure. Thus, note that the quoted portion of Balazs comes under the heading (column 15, lines 3-4):

> "2. Separation of tissue surfaces with a biological prosthesis."

The first sentence thereafter reads:

> "...HUA can be used to separate tissue surfaces..."

Then comes the above-quoted section. Thereafter, Balazs gives four examples:

> "...a. The use of HUA in retinal detachment surgery has two purposes. It provides the surgeon with a visco-elastic tool in the manipulation necessary for reattachment of the retina, and it facilitates the intraocular wound healing by

> preventing excessive fibrous tissue formation and development of intravitreal scar tissue (preretinal organizations, membranes, bands)[1].
>
> [1] Regnault et al., Mod. Probl. Ophthal., Vol. 12, pps. 378-383 (1974); Acta Ophthalmologica, Vol. 49 (1971) pps. 975-6; Edmund, J., Mod. Probl. Ophthal., Vol. 12, pps. 370-377 (1974).
>
> "b. The use of HUA as a biological prosthesis in the anterior chamber is indicated after cataract surgery in order to push back prolapsed vitreous and, after resection of the anterior face of the vitreous, to provide separation between the vitreous and cornea.
>
> "c. This biological prosthesis (HUA) can be used in the anterior chamber after keratoplasty to prevent adhesion formation between the corneal wound and the iris.
>
> "d. This biological prosthesis (HUA) can be used for the separation of tissue surfaces (endothelial or connective tissue) to promote fistula formation. When a new channel for liquid passage must be formed or a blocked channel has to be re-formed, the insertion of HUA jellies or dry membranes can help prevent the development of scar tissue during healing. Development of fistulae between the anterior chamber and subconjunctival space may be facilitated in this way in glaucoma surgery..." [Emphasis added.]

The clear implication of this entire disclosure of Balazs is one of the use of HUA after the surgery has been initiated for prosthetic purposes. There is not even a hint of coating any surfaces involved in the surgery with HUA prior to initiation of the surgical procedure.

It should be obvious that the Examiner is twisting the clear meaning of the language of Balazs to fit his purposes in making this ground of rejection. A skilled artisan reading this disclosure would not be led to a conclusion that the HUA disclosed by Balazs should be applied prior to any manipulation of the tissue in the surgical process. Rather, the skilled artisan would be led to conclude that the disclosed HUA should be utilized well after the surgery has started as a prosthetic device. Note also the disclosures in Balazs cited at pages 11-12 of appellants' Brief.

Again, it is important to bear in mind that the Examiner is not stating that it would be prima facie obvious from Balazs or any other reference to initiate the application of HUA prior to surgery. Rather, the Examiner is stating that Balazs anticipates the claimed method in this regard. As demonstrated above, however, such is not the case.

It is also noted that the Examiner has not addressed the statement in the paragraph bridging pages 13 and 14 of the Brief to the effect that claims with this same limitation were allowed over Balazs in application Serial Nos. 555,377 and 696,960.

Nor is the distinction between application prior to rather than during surgery inconsequential. In the above-noted applications, as well as in the examples herein at pages 23-28 of the specification, it is demonstrated that coating

the surfaces involved in surgery prior to any manipulation of tissue in the surgical procedure gives rise to a totally unexpected, unobvious and unpredictable degree of tissue protection.

In summary, therefore, the following is clear:

(1) The basis for the stated ground of rejection has not properly been set forth by the Examiner.

(a) If the rejection is based on 35 USC §103, the Examiner has not identified the point of novelty in the claimed method, nor shown how it is prima facie obvious over the reference.

(b) If the rejection is based on 35 USC §102 (which, according to the language used by the Examiner, it appears to be), it is improperly stated in the final Office Action, thereby requiring a restatement thereof under 37 CFR §1.193(b).

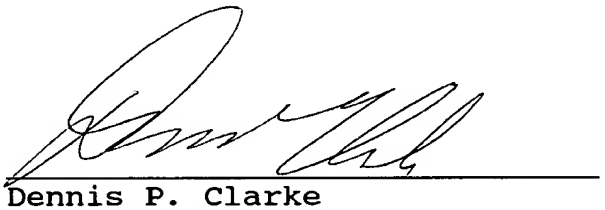
(2) The Examiner has misinterpreted the reference as to just when during the surgical procedure Balazs applies the HUA.

(3) If the Board is able to discern in the confusing discrepancy between the final Office Action and Examiner's Answer, the establishment of a prima facie case of obviousness, any such case is satisfactorily rebutted by the

evidence of record which demonstrates the unobvious and unexpected advantages associated with the claimed invention.

Respectfully submitted,

KERKAM, STOWELL,
KONDRACKI & CLARKE, P.C.



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